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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/708,432

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Thomas Plummer

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

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DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/708,432	Applicant(s) PLUMMER ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-16 is/are rejected.
- 7) ☒ Claim(s) 8 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawn Objections and Rejections

- The issues raised in the objection to the specification have been addressed therefore the objection is hereby withdrawn.
- The objection to claim 3 is hereby withdrawn since claim 2, which was substantially the same, has been cancelled.
- The confusing description of the polymeric structure claimed in claim 5 has been amended therefore the objection to this claim is hereby withdrawn.
- Modifications to the language in claims 11-12 and 14-15 have been made therefore the objections to these claims are hereby withdrawn.
- The relative terminology in claims 1, 5, and 10-11 has been removed so the rejections of these claims under 35 U.S.C. 112, second paragraph for this issue are hereby withdrawn.
- The language in claims 2-3 and 12-15 that was indefinite has been amended therefore the rejections of these claims under 35 U.S.C. 112, second paragraph are hereby withdrawn.

Response to Arguments

Applicants' arguments, filed May 30, 2008, have been fully considered but they are not deemed to be persuasive. The applicant cites a passage in Phipps that teaches that some acids can introduce competing ions in the system and that this statement teaches away from using an amino acid as a buffer in the taught device. This statement in Phipps goes on to say that the issue of competing ions from acids only occurs when the cathode is the donor electrode (see column 7 lines 21-46). In the case of the cited examples, a cationic medicament is delivered (e.g. lidocaine HCl) and thus to deliver this drug the anode would be the donor electrode (see column 1 lines 47-50). Further, Since Phipps teaches the combination of anionic buffering agents with cationic buffering agents, citing both amino acids and polymeric buffers in both categories, it would have

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been well with the technical grasp of one of ordinary skill in the art to provide a buffering system that combines a polymeric buffer with an amino acid.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 8 and 15 are objected to because of the following: Each claim contains trademark. The use of the trademark Tween® 20A and WATER LOCK® A220 has been noted in this application. It should be capitalized wherever it appears and *be accompanied by the generic terminology.*

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

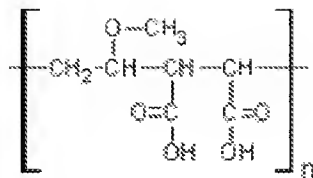
The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim discloses a chemical structure that is supposed to depict a polymer however, no portion of the structure has been indicated as the repeating unit, thus the structure recited is not actually a polymer and makes the claim indefinite.

For the sake of application of prior art, the structure is being interpreted to be poly(methylvinyl ether maleic acid) which could be depicted as follows, where n is and integer greater than or equal to 2.

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Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim does not state where the pH is maintained.

For the sake of application of prior art the claim is interpreted such that the recited pH is maintained in the matrix of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-5, and 7, 10-11, 13-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps (US Patent No. 5,533,971) in view of the Table of pKa and PI values for amino acids (<http://www.mhhe.com/physsci/chemistry/carey5e/Ch27/ch27-1-4-2.html>).

Phipps teaches an electrotransport device where the pH of the reservoirs is optimized to reduce skin irritation both before and after electrotransport drug delivery

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(see column 3 lines 60-64). In addition, Phipps teaches that iontophoresis is a widely used process of electrotransport. Phipps generally teaches that these devices have one electrode that is termed a donor or active electrode while the other is the counter or return electrode, serving to close the circuit through the body (see column 1 lines 43-47; instant claim 4). The device is configured where an electrical power source is connected to the donor (active) electrode, which includes the donor reservoir with the drug to be delivered (see column 5 lines 34-39; instant claims 1 and 4). Phipps goes on to further describe the donor and counter reservoirs used in the invention. Both are taught as polymeric gel matrices that can include polymers in combination such as KLUCEL®, a hydroxypropyl cellulose and a viscosity enhancer exemplified by the instant application, as well as hydroxyethyl cellulose (see column 17 lines 10-13 and 26, and 32-33; instant claims 1, 7, and 14 and instant specification paragraph 17 line 14-16). WATER LOCK® is also taught in this group of suitable polymers and is also taught as a rehydrating agent in the instant specification (see column 17 lines 24-25; instant specification paragraph 17 lines 17-19). Polymeric buffers are taught by Phipps for use in the anodic reservoir to eliminate competition between the drug to be delivered and the counter ions that can be produced by some buffers (see column 15 lines 7-17). In particular, poly(methylvinyl ether-maleic acid), sold commercially as Gantrez S95 and S97, is given as a particularly envisioned example of such a polymeric buffer, and is also exemplified in the instant specification (see table 7; instant claim 5 specification paragraph 15). As the anodic reservoir is taught to be maintained at pH 4 or greater (approximately 4.5), its exemplified buffers are capable of performing this function (see column 15 lines 59-65; instant claims 1, 10, and 16). It is also taught that the combination of anionic and cationic buffers can be used where amino acids are particularly envisioned in either role (see column 14 lines 25-27). The teachings of Phipps do not explicitly describe the combination of acidic polymeric buffer and a basic amino acid; however, the range over which poly(methylvinyl ether-maleic acid) buffers is nearly the same as that of the acids exemplified. In addition, since both amino acids and polymeric buffers are taught to be available in cationic or anionic form, it would have

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been obvious to one of ordinary skill in the art at the time the invention was made to combine a polymeric buffer with an amino acid buffer.

Glycine (exemplified by applicant's disclosure) is not specifically taught by Phipps as a basic amino acid suitable for use in the invention, however the pKa of its ammonium ion is near that of histidine (see Table of pKa and PI values for amino acids), which is included in the list taught by Phipps. Since the pKa of a compound controls its ability to buffer, the closeness of glycine's value (9.6) to histidine's value (9.17) makes them equivalents for the purposes of the invention of Phipps. Thus amino acids with equivalent buffering function to those exemplified by the applicant were taught by Phipps. Consequently, the combination of polymeric buffers with amino acids would have been a known option within the technical grasp of one of ordinary skill in view of the teachings of Phipps. Such a combination would then make obvious the instant invention. Further, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for the combination of an amino acid with a polymeric buffer (e.g. a cationic amino acid with an anionic polymeric buffer) as an appropriate buffering system in the invention of Phipps and achieve the instantly claimed invention (see instant claims 13 and 16).

Phipps goes on to discuss the classifications of drugs (medicaments) that can be delivered by the invention (see column 18 line 43-column 19 line 45). An example teaches a polyvinyl alcohol based hydrogel that contains lidocaine HCl (medicament) and is used to deliver the drug to a living patient through the skin; here, the potassium concentration is monitored as an indicia of skin irritation and to indicate the need to reposition the device (see example 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make and use the invention of Phipps where the polymeric gel matrix includes a polymeric and amino acid buffering (maintaining the pH at approximately 4.5), viscosity enhancer, rehydrating agent and medicament with an active electrode assembly configured for iontophoretic delivery and of the medicament to a living subject's body. In addition it also would have been obvious to also have a power source and a counter electrode that completes the circuit between the active electrode and power source through the body. Therefore, claims 1, 4-5, 7, 10-

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11, 13-14, and 16 are obvious over Phipps in view of the Table of pKa and PI values for amino acids.

Claims 1, 3, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids as applied to claims 1, 4-5, 7, 10-11, 13-14, and 16 above, and further in view of the lidocaine record in the Merck Index.

Phipps makes obvious a device that is used to iontophoretically deliver a medicament to a living subject's body where the device includes polymeric gel matrix reservoir, a polymeric and amino acid buffering system (maintaining the pH at approximately 4.5), viscosity enhancer, rehydrating agent and medicament. Phipps also teaches the incorporation of several classes of drugs (medicaments) that includes anesthetic (see column 18 lines 43-45 and 53-54) In a particular example, Phipps teaches the delivery of the anesthetic lidocaine HCl, a derivative of lidocaine commonly used in the art (see Phipps-example 7 and Lidocaine - Merck Index). As the HCl derivative of lidocaine is commonly used for lidocaine in the pharmaceutical art, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use lidocaine as the medicament in the invention of Phipps. Thus, claims 1, 3, 10, and 12 are obvious over Phipps in view of the Table of pKa and PI values for amino acid and the lidocaine record in the Merck Index.

Claims 1, 3, 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids as applied to claims 1, 4-5, 7, 10-11, 13-14, and 16 above, and further in view of Parkinson et al. (PGPub No.US2003/0023228).

Phipps makes obvious a device that is used to iontophoretically deliver a medicament to a living subject's body where the device includes polymeric gel matrix reservoir, a polymeric and amino acid buffering system (maintaining the pH at approximately 4.5), viscosity enhancer, rehydrating agent and medicament. Phipps also teaches the incorporation of several classes of drugs (medicaments) that includes anti-

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inflammatory compounds (see column 18 lines 43-45 and 56) Phipps does not teach the particular type of anti-inflammatory compound to use in the invention. Parkinson et al. teach an iontophoretic device for delivery of anti-inflammatory steroids that includes water-soluble forms of dexamethsone in particular (see paragraph 4 lines 1-21, paragraph 16 and paragraph 17). It would have therefore been obvious to one of ordinary skill in the art to use dexamethasone in the polymeric gel reservoir matrix in the invention of Phipps.

Phipps also does not teach the particular type of active electrode assembly to employ for the donor electrode. Parkinson et al. teach that in an iontophoretic device the active electrode assemblies can be open faced as well as high-density electrodes (see paragraph 16 and paragraph 37 lines 11-13) It would have therefore been obvious to one of ordinary skill in the art to use open faced or high-density electrodes as the active electrode assembly used with the polymeric gel reservoir matrix in the invention of Phipps. Thus claims 1, 3, 9-10, and 12 are obvious over Phipps in view of the Table of pKa and PI values for amino acid and Parkinson et al.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids as applied to claims 1, 4-5, 7, 10-11, 13-14, and 16 above, and further in view of Hsu et al. (PGPub No. US 2003/0161870).

Phipps makes obvious a device that is used to iontophoretically deliver a medicament to a living subject's body where the device includes polymeric gel matrix reservoir, a polymeric and amino acid buffering system (maintaining the pH at approximately 4.5), viscosity enhancer, rehydrating agent and medicament. Phipps also teaches the incorporation of additional ingredients in the reservoir matrix such as permeability enhancers, but does not teach particular examples of chemicals that could serve in this role. Hsu et al. teach that a variety of compounds are used in the art of drug delivery to enhance skin permeability that includes TWEEN® 20 (see paragraph 5 lines 1-3 and 11). It would have therefore been obvious to one of ordinary skill in the art to use TWEEN® 20 as a permeability enhancer in the polymeric gel matrix in the

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invention of Phipps. Thus claims 1 and 8 are obvious over Phipps in view of the Table of pKa and PI values for amino acids and Hsu et al.

Claim 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids as applied to claims 1, 4-5, 7, 10-11, 13-14, and 16 above, and further in view of the Grain Processing Corporation WATER LOCK Superabsorbent Polymers reference.

Phipps teaches a device configured for iontophoretic delivery that includes polymeric gel matrix reservoir, a buffering agent (maintaining the pH above pH 4 for the anode), viscosity enhancer, rehydrating agent and medicament with an active electrode assembly configured for delivery of the medicament to a living subject's body. In a particular embodiment, Phipps teaches a polyvinyl alcohol (polymer gel matrix) with hydroxypropylmethylcellulose (viscosity enhancer and rehydrating agent) (see column 26 lines 54-58). Phipps also teaches other polymers such as KLUCEL® and WATER LOCK®, that are useful both individually and in combination, as components in the electrode reservoirs (see column 17 lines 10-13 and 26, and 32-33; instant specification paragraph 17 line 14-16). Phipps does not teach a particular variety of WATER LOCK®, but instead implies that any would be suitable. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ WATER LOCK® A220, as a finite number of variants are available and all serve the purpose of absorbing water (see the Grain Processing Corporation WATER LOCK® Superabsorbent Polymers reference). Therefore claims 10 and 15 are obvious over Phipps in view of (see Grain Processing Corporation WATER LOCK® Superabsorbent Polymers).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-83738373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615